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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,332	09/30/2003	Frank Richard Cichocki JR.	ETH5091	4635

27777 7590 06/12/2007
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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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06/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/674,332	Applicant(s) CICHOCKI, FRANK RICHARD	
	Examiner Natalie Pous	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/16/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Regarding The Abstract

Examiner acknowledges amendment to the abstract to address the issue raised. Thus, the previous objection to the abstract is withdrawn.

Regarding The Claim Rejections

Applicant's arguments with respect to claim 1, 2 and 15 have been considered but are moot in view of the new ground(s) of rejection based on amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 4981149) in view of Hubbard (3308820) and further in view of McGregor et al. (US 5649961).

Yoon teaches a hollow suturing needle (60) comprising an internal cavity wherein a drug to be dispensed can be released by holes extending through walls communicating with the lumen and sealed in the suture needle by attachment of suture material which does not extend the length of the lumen, and wherein the fluid may be an antibiotic (Column 7, proximate lines 4-20).

Yoon fails to teach a compressed gas residing between the fluid and the non-hollow portion or seal. Hubbard teaches a device having an internal cavity therein comprising: a proximal end (18), a distal end (16), a point on the distal end (fig. 2), an opening at or in the proximity of the distal end, and a non-hollow portion or seal at or adjacent to the proximal end (16); wherein the internal cavity is in fluid communication with said opening at one end and terminates at said non-hollow portion or seal at the other end (fig. 1); a fluid (M) residing within the internal cavity; and a compressed gas (G) residing between the fluid (M) and the non-hollow portion or seal (18), (Columns 3-4, proximate lines 60-75 and 1-5 respectively), in order to provide a disposable fluid dispensing device that is simple to manufacture and provides effective ejection of medicine from the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Yoon with the pressurized gas ejection mechanism of Hubbard in order to provide a disposable needle that is simple to manufacture and provides effective ejection of medicine from the device.

The combination of Yoon and Hubbard fails to teach wherein the suture is formed of metal. McGregor teaches a suture needle wherein the needle is formed of metal in order to provide a material having sufficient strength to perform procedures without

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breakage or deformation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Yoon and Hubbard with a needle made of metal for non-endoscopic procedures such as suturing skin in order to provide a needle with sufficient strength to perform procedures without breakage or deformation. The limitation wherein the device is made of metal tubing is being treated as a product by process limitation, in that the "wherein the suture needle is produced from metal tubing" refers to the process of making the device and not to the final product created. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP §2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

It appears the product disclosed by the combination of Yoon, Hubbard and McGregor would be the same and would perform equally well as that *claimed*; especially since both applicant's product and the prior art have the same final shape and structure of a needle being formed from tubing, i.e. having a channel there through.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tan-Uyen (Jackie) Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
6/4/07


(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
6/7/07